<center>REMARKS</center>

Claims 1-3, 19, 21, 22, 24, 26-30, 34-41 and 53-73 were pending in the application. Claim 53 was cancelled without prejudice or disclaimer. Hence, claims 1-3, 19, 21, 22, 24, 26-30, 34-41 and 54-73 are pending.

Claims 1-3, 19, 21, 22, 24, 26-30 and 34-41 are withdrawn from further consideration. Claims 54-70 are objected to. Claim 53 is rejected under 35 U.S.C. §102(b). Claims 54 and 56 are rejected under 35 U.S.C. §102(b), or, in the alternative, under 35 U.S.C. §103(a). Claims 53-60 and 71-73 are rejected under obviousness-type double patenting.

Applicants address these objections and rejections below.

I.   CLAIM OBJECTIONS:

The Examiner has objected to claims 54-70 because of various informalities listed on page 2 of the present Office Action. Applicants have amended claims 54, 55, 56 and 60 as recommended by the Examiner on page 2 of the present Office Action. Accordingly, Applicants respectfully request the Examiner to withdraw the objections to claims 54-70.

Claims 54, 55, 56 and 60 were amended, as indicated above, to correct typographical mistakes and not to overcome prior art. Further, claims 54 and 71 were amended, as indicated above, to be rewritten in independent form and not to overcome prior art. Hence, no prosecution history estoppel arises from the amendments to claims 54, 55, 56, 60 and 71. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 U.S.P.Q.2d 1705, 1711-12 (2002); 56 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2000). Further, the amendments made to claims 54, 55, 56, 60 and 71 were not made for a substantial reason related to patentability and therefore no prosecution history estoppel arises from such amendments. *See Festo Corp.*, 62 U.S.P.Q.2d 1705 at 1707 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 41 U.S.P.Q.2d 1865, 1873 (1997).

II.   REJECTIONS UNDER 35 U.S.C. §102(b):

        The Examiner rejects claim 53 under 35 U.S.C. §102(b) as being anticipated by Skinner (U.S. Patent No. 5,709,214), or, alternatively, Ambos et al. (U.S. Patent No. 4,680,708) (hereinafter "Ambos"). Applicants cancelled claim 53, and hence the rejection to claim 53 is moot.

III.   REJECTIONS UNDER 35 U.S.C. §102(b)/§103(a):

        The Examiner rejects claims 54 and 56 under 35 U.S.C. §102(b) as being anticipated by Ambos, or, alternatively, under 35 U.S.C. §103(a) as being obvious over Ambos. Applicants respectfully traverse these rejections for at least the reasons stated below.

        Applicants respectfully assert that Ambos does not disclose or teach "determining characteristic points where said digital signal reaches maximums, minimums, or changes direction" as recited in claim 54. As understood by Applicants, the Examiner cites columns 4 and 5 of Ambos as teaching the above-cited claim limitation. Office Action (1/8/2007), pages 3-4. Applicants respectfully traverse.

        Ambos instead teaches that the R-R interval is compared with the template R-R interval 406. Column 4, lines 27-28. Ambos further teaches if the R-R interval is not within ± 20% of the template value the beat is rejected. Column 4, lines 28-30. Ambos additionally teaches that otherwise, the peak to peak amplitudes of the x, y, and z signals of the chosen beat are compared with the QRS amplitudes of the template 410. Column 4, lines 30-33. Furthermore, Ambos teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected 412. Column 4, lines 33-36. Ambos further teaches that then a 40 point cross correlation 414 of the R wave is made with the template waveform about the fiducial point 208. Column 4, lines 36-38. Hence, Ambos teaches comparing the R-R interval with the template R-R interval and rejecting the beat if the R-R interval is not within ± 20% of the template value. Ambos further teaches that if at least 2 of the 3 amplitudes are the same as the

template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected.

There is no language in the cited passage that teaches <u>determining characteristic points where the digital signal reaches maximums, minimums, or changes direction</u>. Applicants respectfully request the Examiner to particularly point out where Ambos teaches determining characteristic points where the digital signal reaches <u>maximums, minimums, or changes direction</u> pursuant to 37 C.F.R. §1.104(c)(2). Thus, Ambos does not disclose all of the limitations of claim 54, and thus Ambos does not anticipate claim 54. M.P.E.P. §2131. Further, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 54, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

Applicants respectfully assert that Ambos does not disclose or teach "analyzing noise level in said digital signal" as recited in claim 54. As understood by Applicants, the Examiner cites columns 4 and 5 of Ambos as teaching the above-cited claim limitation. Office Action (1/8/2007), pages 3-4. Applicants respectfully traverse.

Ambos instead teaches that the R-R interval is compared with the template R-R interval 406. Column 4, lines 27-28. Ambos further teaches if the R-R interval is not within ± 20% of the template value the beat is rejected. Column 4, lines 28-30. Ambos additionally teaches that otherwise, the peak to peak amplitudes of the x, y, and z signals of the chosen beat are compared with the QRS amplitudes of the template 410. Column 4, lines 30-33. Furthermore, Ambos teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected 412. Column 4, lines 33-36. Ambos further teaches that then a 40 point cross correlation 414 of the R wave is made with the template waveform about the fiducial point 208. Column 4, lines 36-38. Hence, Ambos teaches comparing the R-R interval with the template R-R interval and rejecting the beat if the R-R interval is not within ± 20% of the template value. Ambos further teaches that if at least 2 of the 3 amplitudes are the same as the

template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected.

There is no language in the cited passage that teaches analyzing a <u>noise level</u> in the digital signal. Applicants respectfully request the Examiner to particularly point out where Ambos teaches analyzing a <u>noise level</u> in the digital signal pursuant to 37 C.F.R. §1.104(c)(2). Thus, Ambos does not disclose all of the limitations of claim 54, and thus Ambos does not anticipate claim 54. M.P.E.P. §2131. Further, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 54, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

Applicants further assert that Ambos does not disclose or teach "determining a plurality of pulsometric parameters" as recited in claim 54. As understood by Applicants, the Examiner cites columns 4 and 5 of Ambos as teaching the above-cited claim limitation. Office Action (1/8/2007), pages 3-4. Applicants respectfully traverse.

Ambos instead teaches that the R-R interval is compared with the template R-R interval 406. Column 4, lines 27-28. Ambos further teaches if the R-R interval is not within ± 20% of the template value the beat is rejected. Column 4, lines 28-30. Ambos additionally teaches that otherwise, the peak to peak amplitudes of the x, y, and z signals of the chosen beat are compared with the QRS amplitudes of the template 410. Column 4, lines 30-33. Furthermore, Ambos teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected 412. Column 4, lines 33-36. Ambos further teaches that then a 40 point cross correlation 414 of the R wave is made with the template waveform about the fiducial point 208. Column 4, lines 36-38. Hence, Ambos teaches comparing the R-R interval with the template R-R interval and rejecting the beat if the R-R interval is not within ± 20% of the template value. Ambos further teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected.

There is no language in the cited passage that teaches determining a plurality of pulsometric parameters. Applicants respectfully request the Examiner to particularly point out where Ambos teaches determining a plurality of pulsometric parameters pursuant to 37 C.F.R. §1.104(c)(2). Thus, Ambos does not disclose all of the limitations of claim 54, and thus Ambos does not anticipate claim 54. M.P.E.P. §2131. Further, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 54, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

Further, as understood by Applicants, the Examiner asserts that the teaching of an ST segment in Ambos is equivalent to the teaching of a plurality of pulsometric parameters. Office Action (1/8/2007), page 4. Applicants respectfully traverse. The Examiner must provide a basis in fact and/or technical reasoning to support the assertion that the teaching of an ST segment in Ambos is equivalent to the teaching of a plurality of pulsometric parameters. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). That is, the Examiner must provide extrinsic evidence and must make clear that the teaching of an ST segment in Ambos is equivalent to the teaching of a plurality of pulsometric parameters, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented either a *prima facie* case of anticipation or obviousness for rejecting claims 54. M.P.E.P. §§2131, 2143.

Applicants further assert that Ambos does not disclose or teach "determining significant R-R intervals" as recited in claim 54. As understood by Applicants, the Examiner cites columns 4 and 5 of Ambos as teaching the above-cited claim limitation. Office Action (1/8/2007), pages 3-4. Applicants respectfully traverse.

Ambos instead teaches that the R-R interval is compared with the template R-R interval 406. Column 4, lines 27-28. Ambos further teaches if the R-R interval is not within ± 20% of the template value the beat is rejected. Column 4, lines 28-30. Ambos additionally teaches that otherwise, the peak to peak amplitudes of the x, y, and z signals of the chosen beat are compared with the QRS amplitudes of the

template 410. Column 4, lines 30-33. Furthermore, Ambos teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected 412. Column 4, lines 33-36. Ambos further teaches that then a 40 point cross correlation 414 of the R wave is made with the template waveform about the fiducial point 208. Column 4, lines 36-38. Hence, Ambos teaches comparing the R-R interval with the template R-R interval and rejecting the beat if the R-R interval is not within ± 20% of the template value. Ambos further teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected.

There is no language in the cited passage that teaches determining significant R-R intervals. Thus, Ambos does not disclose all of the limitations of claim 54, and thus Ambos does not anticipate claim 54. M.P.E.P. §2131. Further, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 54, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

Applicants further assert that Ambos does not disclose or teach "averaging the plurality of pulsometric and QRS-complex parameters for a number of significant R-R intervals" as recited in claim 54. As understood by Applicants, the Examiner cites columns 4 and 5 of Ambos as teaching the above-cited claim limitation. Office Action (1/8/2007), pages 3-4. Applicants respectfully traverse.

Ambos instead teaches that the R-R interval is compared with the template R-R interval 406. Column 4, lines 27-28. Ambos further teaches if the R-R interval is not within ± 20% of the template value the beat is rejected. Column 4, lines 28-30. Ambos additionally teaches that otherwise, the peak to peak amplitudes of the x, y, and z signals of the chosen beat are compared with the QRS amplitudes of the template 410. Column 4, lines 30-33. Furthermore, Ambos teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected 412. Column 4, lines 33-36. Ambos further teaches that then a 40 point cross correlation 414 of the R wave is

made with the template waveform about the fiducial point 208. Column 4, lines 36-38. Hence, Ambos teaches comparing the R-R interval with the template R-R interval and rejecting the beat if the R-R interval is not within ± 20% of the template value. Ambos further teaches that if at least 2 of the 3 amplitudes are the same as the template amplitudes then the beat is selected as a candidate for averaging, otherwise the beat is rejected.

There is no language in the cited passage that teaches averaging the plurality of pulsometric and QRS-complex parameters. Neither is there any language in the cited passage that teaches averaging the plurality of pulsometric and QRS-complex parameters for a number of significant R-R intervals. Thus, Ambos does not disclose all of the limitations of claim 54, and thus Ambos does not anticipate claim 54. M.P.E.P. §2131. Further, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 54, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

Claim 56 recites combinations of features of independent claim 54, and hence claim 56 is not anticipated by Ambos and is patentable over Ambos for at least the above-stated reasons that claim 54 is not anticipated by Ambos and is patentable over Ambos. Claim 56 recites additional features, which, in combination with the features of claim 54 upon which it depends, is not anticipated by Ambos and is patentable over Ambos.

For example, Ambos does not disclose or teach "calculating the noise level N for a current R-R interval; comparing the noise level with a threshold value; and excluding said current R-R interval if said noise level exceeds said threshold value" as recited in claim 56. As understood by Applicants, the Examiner admits that Ambos does not specifically recite these claim limitations. Office Action (1/8/2007), page 4. However, the Examiner asserts that these limitations are well known in the art. *Id*. Applicants respectfully traverse that these limitations are well known in the art and respectfully request the Examiner to provide a reference that teaches calculating the noise level N for a current R-R interval; comparing the noise level

with a threshold value; and excluding the current R-R interval if the noise level exceeds the threshold value pursuant to M.P.E.P. §2144.03.

Further, the Examiner is reminded that in order to establish a *prima facie* case of obviousness the Examiner must provide some suggestion or motivation, either in the references themselves, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved, to modify the reference or to combine reference teachings. *See In re Dembiczak*, 175 F.3d 1994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Examiner states "to determine if the signal is or is not noisy and if the signal should be used for processing since noisy signals may falsely indicate a serious heart condition or mask a serious heart condition" as motivation. <u>Applicants respectfully request the Examiner to point out which of these sources is the source of the Examiner's motivation</u>[1]. The Examiner has not provided any evidence that his motivation comes from any of the sources listed above. Instead, the Examiner is relying upon his own subjective opinion which is insufficient to support a *prima facie* case of obviousness. *In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002). Consequently, the Examiner's motivation is insufficient to support a *prima facie* case of obviousness for rejecting claim 56. *Id.*

Further, the Examiner's motivation may provide a reason for performing the limitations but that does not necessarily imply a reason for modifying Ambos to perform the missing claim limitations.

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[1] Applicants feel it is very important for the Examiner to point out the source of the Examiner's motivation because it appears to Applicants that the Examiner is relying upon his own subjective opinion. The reason why the Federal Circuit (*In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2000)) has required the Examiner to provide objective evidence is because it may be easy to conclude that it would be obvious to combine references using hindsight reasoning even though there is no motivation or suggestion to do so. One can usually find a reason to combine references or make modifications to the main reference. If that were all it took, then all inventions would be obvious and not patentable. For example, assuming that a wheelbarrow had never been developed and a patentee had claimed a wheelbarrow, if the main reference taught a cart with a shallow box body, and the secondary reference taught two wheels, then the Examiner could simply assert, using hindsight reasoning without providing objective evidence, that the motivation for combining the two references is so that the cart could be moved from place to place. Hence, the patentee could not obtain a patent on the wheelbarrow (even though one has never been developed) based on the Examiner's rationale for combining the references. Yet the Examiner has not provided any evidence that a person of ordinary skill in the art would have combined the references to make such a product. In hindsight, everything is obvious. It seems that a question that should be asked is why the invention (in this example a wheelbarrow) was not already developed. If it is so obvious, then it would seem it already would have been developed.

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Therefore, an Examiner may often find every element of a claimed invention in the prior art. *Id*. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See Id*. In order to establish a *prima facie* case of obviousness, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). That is, the Examiner must provide some suggestion or motivation, either in the references themselves, the knowledge of one of ordinary skill in the art, or, in some case, the nature of the problem to be solved, to modify the reference or to combine reference teachings. *See In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Whether the Examiner relies on an express or an implicit showing, the Examiner must provide particular findings related thereto. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

The Examiner' motivation ("to determine if the signal is or is not noisy and if the signal should be used for processing since noisy signals may falsely indicate a serious heart condition or mask a serious heart condition") does not provide reasons, as discussed further below, that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Ambos to include the above-indicated missing claim limitations of claim 56. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 56. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

Ambos addresses the problem of providing a noninvasive electrocardiographic system capable of improved object identification and characterization of low amplitude potentials in the surface ECG signal. Column 1, lines 54-57. The Examiner has not provided any reasons as to why one skilled in the art would modify Ambos (which teaches providing a noninvasive electrocardiographic system capable

of improved object identification and characterization of low amplitude potentials in the surface ECG signal) to: (1) calculate the noise level N for a current R-R interval; (2) compare the noise level with a threshold value; and (3) exclude the current R-R interval if the noise level exceeds the threshold value (missing claim limitations). The Examiner's motivation ("to determine if the signal is or is not noisy and if the signal should be used for processing since noisy signals may falsely indicate a serious heart condition or mask a serious heart condition") does not provide such reasoning.

Why would the reason to modify Ambos (whose purpose is to provide a noninvasive electrocardiographic system capable of improved object identification and characterization of low amplitude potentials in the surface ECG signal) to: (1) calculate the noise level N for a current R-R interval; (2) compare the noise level with a threshold value; and (3) exclude the current R-R interval if the noise level exceeds the threshold value (missing claim limitations) be to determine if the signal is or is not noisy and if the signal should be used for processing since noisy signals may falsely indicate a serious heart condition or mask a serious heart condition? Ambos is not concerned with determining if a signal is noisy or not. While reducing noise in a signal may improve the accuracy of the signal, why does this necessarily conclude to calculate the noise level N for a current R-R interval? Further, while reducing noise in a signal may improve the accuracy of the signal, why does this necessarily conclude to compare the noise level with a threshold value? Further, while reducing noise in a signal may improve the accuracy of the signal, why does this necessarily conclude to exclude the current R-R interval if the noise level exceeds the threshold value? Hence, the Examiner's motivation does not provide reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Ambos to include the missing claim limitations of claim 56. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 56. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

IV.   DOUBLE PATENTING REJECTION:

The Examiner has rejected claims 53-60 and 71-73 under the judicially created doctrine of obviousness-type double patenting in view of claims 1-29 of U.S. Patent No. 6,656,125. Applicants submit herewith a terminal disclaimer to overcome these rejections. Applicants note that the filing of a terminal disclaimer is not an admission of the proprietary of the non-statutory double patenting rejection. M.P.E.P. §804.02.

V.   ALLOWABLE SUBJECT MATTER:

Applicants thank the Examiner for the indication of allowability of claims 61-70.

VI.   CONCLUSION:

As a result of the foregoing, it is asserted by Applicants that claims 54-73 in the Application are in condition for allowance, and Applicants respectfully request an allowance of such claims.   Applicants respectfully request that the Examiner call Applicants' attorney at the below listed number if the Examiner believes that such a discussion would be helpful in resolving any remaining issues.

Respectfully submitted,

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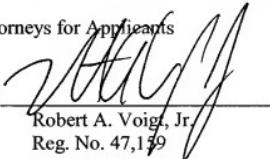
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